

Directions for Use



Preparation of Device & Patient



- In addition to the device kit, gloves, lubricant and water or saline will be required.
- Using the syringe provided, remove the air that is in the balloon by attaching the syringe to the white inflation port (marked “≤45ml”) and withdraw the plunger.



- Remove the supplied syringe and fill it with only 45ml of water or saline and connect the syringe to the white inflation port of the catheter.



- Securely attach the collection bag to the connector at the end of the catheter. The small hook on the catheter is designed to help secure connection from the bag to the connector.
- Use your labels to write insertion date and time. Place on the allocated space at the end of bead strap.

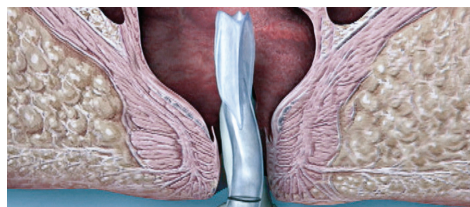


- Position the patient in left side-lying position; if unable to tolerate, position the patient so access to the rectum is possible.
- Perform a digital rectal exam to evaluate suitability for insertion of device.
- The rectum should have adequate anal tone and be free of solid stool or any in-dwelling or anal device prior to insertion.

Insertion of Device



- Unfold the length of the catheter to lay it flat on the bed, extending the collection bag toward the foot of the bed.
- Insert a lubricated gloved finger into the blue finger pocket for digital guidance during device insertion (the finger pocket is located above the position indicator line).
- Coat the balloon end of the catheter with lubricant.



- Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is beyond the external orifice and well inside the rectal vault.
- The finger may be removed or remain in place in the rectum during initial balloon inflation.



- Begin inflating with water or saline by slowly depressing the syringe plunger.
Never inflate the retention balloon with more than 45ml of water.



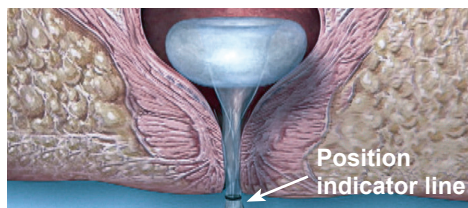
- With the insertion finger removed, the green dome will indicate once the balloon has reached the optimal fill level for the anatomy. Stop inflation once the green dome has signalled optimal fill.
- **Under no circumstances should the balloon be inflated with more than 45ml of fluid.**



- If the PROTECT dome indicates at less than 30ml of fluid, withdraw the fluid and reposition the balloon in the rectal vault.
- After repositioning, fill the balloon as described above.
- **DO NOT fill with more than 45ml of fluid.**
- The red PROTECT indication dome will start to indicate if the balloon is overfilled beyond the maximum 45ml of fluid. If the red PROTECT indication dome is fully inflated, assess patient's position, fully deflate the balloon and repeat the balloon inflation process. Stop inflation once green dome has signalled optimal fill.



- Remove the syringe from the inflation port, and gently pull on the soft catheter to check that the balloon is secure in the rectum and that it is positioned against the rectal floor.
- Take note of the position indicator line relative to the patient's anus.
- Regularly observe changes in the location of the position indicator line as a means to determine movement of the retention balloon in the patient's rectum. This may indicate the need for the balloon or device to be repositioned.



- In the event of expulsion of the device, deflate the balloon fully; rinse the balloon end of the catheter and reinsert following the instructions for 'Insertion of Device'.
- A rectal exam should be conducted prior to re-insertion to verify that no stool is present.
- If expulsion continues for more than three episodes discontinuation of the device should be considered.



- Position the length of the flexible catheter along patient's leg avoiding kinks and obstruction.



- Hang the bag by the bead strap on the bedside at a position lower than that of the patient.

Irrigation, Maintenance & Removal of Device



- To irrigate the device, fill the syringe with water at room temperature, attach the syringe to the BLUE irrigation/medication port (marked “IRRIG./Rx”) and slowly depress the plunger.
- Clinicians should take extra care to use the blue irrigation/medication port only when irrigating.
- **DO NOT irrigate through the white inflation port (marked “≤45ml”) as this would lead to over inflation of the retention balloon and the device would not be irrigated as intended.**



- If repeated flushing with water does not return the flow of stool through the catheter, the device should be inspected to ascertain that there is no external obstruction (i.e. pressure from a body part, piece of equipment, or resolution of diarrhea).
- If no source of obstruction of the device is detected, use of the device should be discontinued.



- Change collection bag as needed.
- Discard used bags according to institutional protocol for disposal of medical waste.
- Observe the device frequently for obstructions from kinks, solid fecal particles or external pressure.



- To remove the catheter from the rectum, the retention balloon must first be deflated.
- Attach the syringe to the white inflation port (marked “≤45ml”) and slowly withdraw all fluid from the retention balloon.
- Disconnect the syringe and discard.
- Grasp the catheter as close to the patient as possible and slowly remove from the anus.
- Dispose of device in accordance with institutional protocol for disposal of medical waste.

Medication Administration



- Attach the supplied syringe and flush the irrigation line with 10ml of water.
- Prepare a new syringe with prescribed medication.
- Position the cinch clamp loosely on the catheter at the black indicator line. Connect syringe to the BLUE irrigation/medication port (“IRRIG./Rx”) and administer medication.
- Clinicians should take extra care to use the blue irrigation/medication port only when delivering medication.



- **DO NOT administer medication through the white inflation port (marked “≤45ml”) as this would lead to over inflation of the retention balloon and the patient would not receive medication as intended.**
- To ensure delivery of medication into the rectum immediately flush the irrigation line with at least 50ml of water.
- Tighten the cinch clamp on the catheter to ensure no flow through the catheter (ensure the second notch is engaged; squeeze tightly using forefinger and thumb of both hands to ensure a good seal).



- Allow the medication to dwell in the rectum for the desired amount of time as dictated by the prescribing physician.
- Remove the cinch clamp.
- Attach a new syringe (not supplied) and flush the irrigation line with 10ml of water.
- Dispose of the syringe according to institutional policy.

Sampling



- To collect a sample from the catheter, open the dark blue sample port cap.
- Press the tip of a Luer-slip syringe (aka catheter tip or “Toomey” syringe) through the slit inside of the sampling port to access the interior of the catheter.
- Withdraw the syringe plunger to collect the sample.
- Withdraw the syringe and close the dark blue sampling port cap.

Directions for Use



Product Description

The Flexi-Seal™ PROTECT Fecal Management System contains:

- 1 soft catheter tube assembly,
- 1 Luer-Lock Syringe,
- 1 collection bag with filter, and 1 cinch clamp

The soft catheter is inserted into the rectum for fecal management to contain and divert fecal waste in order to protect the patient's skin and keep the bedding clean. There is a low-pressure retention balloon at the distal end and a connector for attaching the collection bag at the other end. There is a recess under the balloon for the clinician's finger allowing the device to be positioned digitally.

A blue and a white port are attached to the side of the catheter. The white port, marked "≤45ml" is used to inflate the retention balloon after the device has been inserted into the patient's rectum. This white inflation port is equipped with two fill indicating domes (PROTECT indicator domes), green color (i.e. the dome closest to the catheter tubing) and red color (i.e. the dome furthest from the catheter tubing). The green fill indication dome provides a visual and tactile indication as to when the low pressure retention balloon is filled to its optimal volume. A red-dome fill indicator provides a visual and tactile indication when balloon over-inflation occurs. A white cap is to close off the white inflation port after the balloon inflation. The blue port, marked "IRRIG. /Rx" is used to flush the device if needed and administer medication, if prescribed. A dark blue sampling port is also present if stool samples are required to be taken by the clinician.

Indications

For use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications.

Contraindications

- This product is not intended for use
 - for more than 29 consecutive days
 - for pediatric patients (patients under 18 years of age) as its use has not been tested in this population
- The Flexi-Seal™ PROTECT Fecal Management System should not be used on individuals who
 - have suspected or confirmed rectal mucosal impairment, i.e. severe proctitis, ischemic proctitis, mucosal ulcerations
 - have had rectal surgery within the last year
 - have any rectal or anal injury
 - have hemorrhoids of significant size and/or symptoms
 - have a rectal or anal stricture or stenosis
 - have a suspected or confirmed rectal/anal tumor
 - have any in-dwelling rectal or anal device (e.g. thermometer) or delivery mechanism (e.g. suppositories or enemas) in place
 - are sensitive to or who have had an allergic reaction to any component within the system

Warnings

- Warning:** Clinicians should be aware that there are very limited clinical data on the use of in-dwelling fecal management systems after 14 days continued use.
- Warning:** There is a potential risk of misconnections with connectors from other healthcare applications, such as intravenous equipment, breathing and driving gas systems, urethral/urinary, limb cuff inflation neuraxial devices and other enteral and gastric applications.
- Warning:** Not following these instructions for use may increase the likelihood of an adverse event.
- Warning:** Patients should be monitored daily for and a physician notified immediately if any of the following occur
 - Rectal pain
 - Rectal bleeding
 - Abdominal symptoms such as distension/pain
- Warning:** Over inflation of the retention balloon has the potential to increase the risk of adverse events including rectal pain, bleeding, ulcerations, and possible perforations.
- Warning:** There is a danger of fecal obstructions with this product.

Precautions and Observations

- Close attention should be exercised with the use of the device in patients who have inflammatory bowel conditions or who have had rectal surgery. The physician should determine the degree and location of inflammation or extent of surgery (e.g. location of anastomosis) within the colon/rectum prior to considering use of this device in patients with such conditions.
- Care should be exercised in using this device in patients who have a tendency to bleed from either anti-coagulant / antiplatelet therapy or underlying disease.** If signs of rectal bleeding occur, remove the device immediately and notify a physician.
- The device should be used with caution in patients with spinal cord injury because of the possibility of the development of autonomic dysreflexia.
- Remove any indwelling or anal device prior to insertion of the Flexi-Seal™ PROTECT FMS and do not insert any other devices into the rectum while the Flexi-Seal™ PROTECT FMS is in place.
- Ensure that the patient does not lie or sit on the catheter as this could lead to localised pressure damage and contribute to the development of anal skin breakdown and/or restrict fecal flow.
- Solid or soft-formed stool cannot pass through the catheter and will obstruct the opening. The use of the device is not indicated for solid or soft-formed stool.
- Small amounts of moisture or seepage around the catheter is anticipated. To avoid skin irritation, initiate an appropriate institutional skin care protocol. At a minimum, the skin should be kept clean, dry and protected with a moisture barrier product.
- If the catheter becomes blocked with feces, it can be rinsed with water using the irrigation port only (see Direction for Use "Irrigation of the Device").
Do not use the white inflation port (marked "≤45ml") to irrigate. If obstruction of the catheter is due to solid stool, use of the device should be discontinued.
- Clinicians should take extra care to use the blue irrigation/medication port only when irrigating and delivering medication. DO NOT irrigate or administer medication through the white inflation port (marked "≤45ml").**
- This device is intended for liquid to semi-liquid stool only. Discontinue the use of the device if the patient's bowel control, consistency and frequency of stool begin to return to normal.
- As long as the patient is regularly and closely monitored at all times, patients may be seated for short periods i.e. for up to 2 hours, as part of daily nursing care. During this period of seating, regular monitoring should be made to ensure the tubing is never blocked or kinked and to check for and avoid pressure damage to the anal/peri-anal region. For some patients, the length of the period of seating to avoid pressure damage to the anal/peri-anal region could be much shorter and the clinician should be alert to this possibility.
- As with the use of any rectal device, the following adverse events could occur:
 - Leakage of stool around the device
 - Rectal/anal bleeding due to pressure necrosis ulceration of rectal or anal mucosa
 - Peri-anal skin breakdown
 - Temporary loss of anal sphincter muscle tone
 - Infection
 - Bowel obstruction
 - Perforation of the bowel
- This device is for single use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.
- If there is no flow of stools in a 24 hour period then the following actions should occur:
 - irrigation (see section: Irrigation, Maintenance & Removal of Device) or
 - removal of the device

General Guidelines

- The device may be changed as needed to perform normal patient assessment.
- The device is not intended for use for more than 29 consecutive days.
- If the product packaging or content are visibly damaged, do not use.
- For more detailed instructions refer to the Directions for Use provided in the device package.



Consult instructions for use



Do not re-use



Do not use if packaging is damaged



Rx ONLY



CE

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

Ordering Codes

Flexi-Seal™ PROTECT FMS Kit* (1 kit/box, 1bag)	421630
Privacy™ Collection Bag with APS Filter (10/box)	411108

www.flexi-seal.convatec.com

IFU Training Video

